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INSTITUTIONAL REVIEW BOARD, UNC-CHAPEL HILL

University of North Carolina-Chapel Hill
Consent to Participate in a Research Study
Adult Subjects
Biomedical Form—

IRB Study # 09-1344 **GCRC #: N/A**
Consent Form Version Date: October 4, 2011

Title of Study: Cardiopulmonary Responses to Exposure to Ozone and Diesel Exhaust with Moderate Exercise in Healthy Adults
Principal Investigator: Michael Madden, PhD
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Faculty Advisor: N/A

Funding Source: US Environmental Protection Agency Intramural Federal Research

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What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study, for any reason at any time.

Research studies are designed to obtain new knowledge that may help other people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Your participation is voluntary. Deciding not to be in the study or leaving the study before it is completed will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

We breathe a complex mixture of air pollution, and ozone and diesel exhaust are generally the major and important components. Controlled exposures of volunteers to either pollutant have resulted in biological effects such as lung physiological changes. However it is not known if co-exposure to both pollutants, similar to inhaling polluted air, can induce effects than either pollutant alone. Additionally it is also uncertain if exposure to diesel exhaust alone, or diesel exhaust mixed with ozone, can alter the body's responses to breathing ozone the following day. This study proposes to examine whether exposure to both ozone and diesel exhaust can cause more of an effect than either pollutant alone. This study will also determine if breathing diesel exhaust can change a response upon exposure to ozone the day after. The purpose of this study is to measure cardiopulmonary responses in healthy young adults before, during, and after exposure to combinations of ozone (O3) and diesel exhaust for 2 hours with moderate exercise and to primarily investigate whether diesel exhaust modulates the O3-induced effects on the lung and cardiovascular systems.

This study will examine whether co-exposures to ozone and diesel exhaust, at doses in the upper range of those encountered in urbanized settings, can induce additive or synergistic effects, and whether a previous DE exposure alters a response upon subsequent exposure to ozone.

The data obtained from this study will contribute to the overall assessment of air pollution effects in the U.S. and thereby may influence future health policy. The ambient permissible concentrations of both ozone and diesel exhaust are currently regulated individually by the US EPA, but the Agency is moving towards regulating pollutant mixtures. Results from this study may increase the understanding of how gaseous and particulate air pollutants (which causes the haze seen in some polluted cities) may adversely affect the functioning of the heart, blood vessels, and lungs. This understanding may be especially important for patients with diseases of the heart and lungs.

Are there any reasons you should not be in this study?

You should not participate in this study if…

- You have a history of chest pain, irregular heart beats, a heart attack or coronary bypass surgery.
- You have a heart pacemaker.
- You have untreated high blood pressure (> 150 systolic, > 90 diastolic).
- You have a history of an EKG finding called QT/QT_C prolongation [a marked baseline prolongation of QT/QTc interval (e.g., repeated demonstration of a QTc interval > 450 milliseconds)]
- You have a history of lung disease and/or active allergy including: hay fever, dust allergies, rhinitis, asthma, chronic bronchitis, chronic obstructive pulmonary disease, tuberculosis, coughing up blood, recurrent pneumonia, chronic or allergic rhinitis or acute or chronic sinusitis.
- You cannot perform moderate exercise
- You cannot remain in a small exposure chamber for about 2 hours
- You are currently taking β-blockers (such as atenolol, metoprolol, propanolol, and acebutolol).
- You have a history of bleeding or coagulation disorders or are taking blood thinner medication.
- You are currently smoking or have a smoking history within 1 year of the study (defined as more than one pack of cigarettes in the past year) or have a greater than/equal to a 5 pack year smoking history.
- You are less than 18 years old or greater than 55 years old

- You have diabetes.
- You have cancer.
- You are currently taking estrogen replacement therapy.
- You are pregnant, attempting to become pregnant or breastfeeding.
- You have an allergy to latex.

Additionally, you should **NOT** participate if you are unable to comply with the following requirements:

- No over-the-counter pain medications such as aspirin, Advil, Aleve or other non-steroidal anti-inflammatory medications ("NSAIDS") for 48 hr prior to the exposure and post-exposure visits. Acetaminophen, eg, Tylenol, is permitted.
- Avoid smoke and fumes for 24 hours before all visits.
- Avoid drinking alcohol 24 hours before all visits.
- Avoid strenuous exercise for 24 hours prior to and after all visits.
- Eat a light breakfast on the exposure days.
- Not consume caffeine for 1-2 hours prior to the exposures on days 1 & 2 and post-exposure visits.
- Stop taking vitamin C or E or medications which may impact the results of the exposures at least 2 weeks prior to the study and for the duration of the study. Medications not specifically mentioned here may be reviewed by the investigators prior to your inclusion in this study.
- Avoid the use of ozone-based home air purifiers during study participation

How many people will take part in this study?

If you decide to be in this study, you will be one of approximately 15 people who will complete this research study.

How long will your participation in this study last?

You will have up to 13 visits to the research facility over approximately about 10 weeks if you are eligible for the study (see attached study design flow chart).

Your participation in this study will include one training session (today) for about 3 hours, 4 exposure regimens, each of which will consist of 2 consecutive exposure days and 1 follow-up visit approximately 18 hrs after the last exposure. Each exposure day will last approximately 8 hours and the follow-up visit will be approximately 3 hrs long. The 4 exposure regimens will occur at least 13 days apart.

Storage of some of your blood samples in this study may be indefinite.

What will happen if you take part in the study?

During the course of this study, the following will occur:

Training:

You should have already undergone a general physical examination to ensure that you are a candidate for this study. If you are a female participating in this study, you should have been asked about your menstrual history and will be given a pregnancy test.

Today's visit is expected to last about 3 hours. Today you will familiarize yourself with some of the techniques you will perform for the study. These include instructions on the use of the stationary bicycle to be used during the study, how to perform spirometry, on a portable spirometer and dry seal digital spirometer, how to give a saliva and an exhaled breath sample, and you will be shown the heart rate variability (HRV) and blood pressure (BP) monitors.

After satisfactorily completing the training session, you will be scheduled for your first exposure through a company contracting with the US EPA (currently Westat).

You will be exposed to mixtures of air pollutants in 4 different regimens. Each regimen will last about 2 ½ days. During the regimens, a number of physiological and biochemical measurements will be made. **With your permission, during one of your blood draws DNA from your blood cells will also be genotyped for specific genes related to adverse health effects associated with air pollution exposure. Unwillingness to have samples genotyped will NOT exclude you from participating in this study. If you do not wish for your blood to be used for genotyping, but do wish to participate in the study, sign the section at the end of this consent form titled *Subject's Agreement to Participate in the Research Study WITHOUT Genoptyping Consent.* With your permission, we may also store some of your blood we obtain during the study for yet-to-be-determined tests in the future.**
You will have the opportunity to complete all 4 regimens separated by at least 2 weeks. The first day of each regimen you will be exposed to either clean air, diesel exhaust at about 300 micrograms of particles/meter^3, ozone at about 0.3 parts per million (ppm), or diesel exhaust mixed with ozone. The second day of the regimen, you will be exposed to approximately 0.3 ppm ozone. The third day of each regimen, you will not be exposed to any air pollutants, but will have follow up measurements made.

You may terminate your participation from this study at any time. You will be monitored for symptoms that you may develop during the exposure and over the following 24 hour period. The symptoms may include chest pain, difficulty breathing, light-headness, pale skin color, and significant irregular heart beats. In addition, analyses of blood samples taken after exposure will be monitored for abnormalities, including signs of cell damage, changes in clotting factors, as well as increases in inflammation. The study physicians will stop the study if symptoms and/or changes detected in the blood samples that are considered clinically significant.

Below is a description of what will be required from you and a summary of the measurements to be made on you on each day of each exposure regimen:

Day 1:

We will call you a few days before the exposure session to remind you of your scheduled visit. We will also remind you to refrain from alcohol, NSAID medications, excessive amounts of caffeine, and from any activities where you could be exposed to high levels of pollutants (e.g., cigarette smoke, paint fumes) for a couple of days before your visit. Please report any pollutant

exposure to the study personnel so you can be rescheduled if necessary. You will be rescheduled if you have experienced a respiratory tract illness within the past 4 weeks or any other illness within the past week.

You will be asked to eat a light breakfast and arrive at the EPA medical station at approximately 8 am. There will be an on-time bonus of $25 for arriving by 8:05 a.m. You will need to wear comfortable clothes and shoes and bring a change of clothes.

Pre-exposure measurements:

Prior to the day 1 exposures, you will be asked to do the following:

- Answer a questionnaire on stress
- Have your vital signs checked (heart rate, respiratory rate, blood pressure, and oxygen saturation level, and for women, a pregnancy test).
- Have your baseline heart rate viability (HRV) measured by a Holter monitor. You will have several ECG leads attached to your chest. It may be necessary to clean and shave the areas of your chest where these leads will be placed. Excessive deodorant, skin lotions, and body sprays may interfere with the function of some of these leads so we will ask you not apply these to your chest area on the day you report to the HSF. The leads will be connected to 2 monitors (small recording devices about the size and weight of a portable tape player) to obtain readings of your heart rate and rhythm. One of these monitors will be removed at the end of the day and the other monitor may be kept on you for the next two days and will be removed on Day 3 of the exposure session. You will be asked to recline quietly and breathe at a constant rate for 20 minutes, after which the ECG monitor will take a 10-minute measurement of your heart rhythm. It is important that you do not fall asleep during this 30-minute period. The morning of the follow up visit (Day 3), there may be a 30 minute measurement of your heart rate and then the monitor will be removed.
- Blood pressure (BP) may be measured intermittently by a BP monitor. A blood pressure cuff and a monitor which is about the size of the Holter monitor may be fitted and will remain in place most of the time until Day 3. You will be asked to keep your arm relaxed and still when the pressure cuff is inflating.
- Have about 25 ml blood drawn (~5 teaspoons).
- Have a breathing test (spirometry). .You will breathe through a filter into the machine. We will coach you, and you will be asked to take a full breath in and then blow it out as hard and fast as you can. We will ask you to do this several times. This procedure will be repeated on a portable devise as well.
- Be asked to provide a urine sample; if you are female it will be tested to see if you are pregnant.
- We will collect your breath and saliva.
- You will be asked to collect your urine for the next 24 hrs
- Have a second breathing test on a portable spirometry instrument, but in a similar manner as the first.

During the Day 1 exposure you will:

- Enter an exposure chamber.

- Be exposed to clean air or air pollutants for 2 hours. You will be asked to perform intermittent moderate exercise in an exposure chamber.
- At certain times during the exposure, you may be asked to breathe into a mouthpiece so that your rate of breathing can be measured. In addition, you will be asked to breathe into a portable spirometer so that your lung function can be measured. Exposure may be terminated if you show a larger than expected decrement in lung function. A staff member will be seated outside the chamber to observe you at all times and a physician will be available during the entire exposure session. During the exposure, your heart rhythm and rate, blood pressure, and the amount of oxygen in your blood will be monitored. If it appears you are having heart rhythm or breathing problems, or you develop a severe headache, nausea or vomiting the exposure will be terminated immediately.

Immediately following the Day 1 exposure you will:

- Have your vital signs checked.
- Perform spirometry. You will breathe through a filter into the machine. We will coach you, and you will be asked to take a full breath in and then blow it out as hard and fast as you can. We will ask you to do this several times about 1 assessment each hour
- We will collect your breath and saliva
- You will recline quietly for 20 minutes, after which the ECG monitor will take a 10-minute measurement of your heart rhythm.
- Have blood drawn (about 25 ml; ~5 teaspoons).
- Provide a urine sample.

Later in the day, you will:

- Have spirometry assessed for up to 4 hr post exposure
- Be assessed for adverse responses and discharged by the nursing staff. You will spend about 8 hours at the EPA facility.
- You will be given a cooler containing 1 L plastic bottles and verbal instructions for how to collect and record the time of the urine samples.

Importantly, because you will be asked to wear the portable ECG monitor attached to your chest and a blood pressure monitor cuff on your arm for the following two nights, we will give you instructions on how to care for and remove the monitors when necessary.

Day 2:

You will return to the HSF the next morning at 8:00 a.m. and you will perform testing similar to the first day.

Pre-exposure measurements and procedures will be performed as on Day 1, with the exception of the stress questionnaire. You will then enter the exposure chamber.

During the exposure on Day 2 you will be exposed to ozone at a concentration of approximately 0.3 ppm for 2 hours with intermittent moderate exercise in an exposure chamber. Again, your heart rhythm and rate, blood pressure, the amount of oxygen in your blood, your breathing rate, and lung function will be monitored while you are inside the chamber.

- **Similar measurements and procedures will be performed with you during and following the Day 2 exposure as on Day 1.** However, you will only be asked to collect spot urine samples at the EPA facility. You will be assessed for adverse responses and you will be discharged by the nursing staff. You will spend about 8 hours at the EPA facility.

Day 3:

Follow up Visit:
Similar procedures and measurements will be made as the pre-exposure measurements of the two previous days. The Holter monitor attached to you will be removed. You will be assessed for adverse responses and you will be discharged by the nursing staff. You will spend about 3 hours at the EPA facility.

If there are remaining samples after our analysis, we would like to continue to store your samples for as yet undesignated studies. This allows us to make the best use of the samples we collect from you. You will be given a separate consent form for this storage, and you do not have to allow your samples to be stored in order to participate in this study.

What are the possible benefits from being in this study?
You will not benefit directly from being in this research study, though by participating in screening for this study you will have received a medical examination that included blood work, respiratory test, and ECG monitoring of heart at no charge. However, this is not a substitute for a routine doctor visit. The medical staff will explain to you any remarkable findings regarding your overall health status. In addition, if we observe changes in your health status as a consequence of exposure to air pollutants, you may elect to use this information to avoid exposure on high pollution days.

This research is designed to benefit society in general by gaining new knowledge. Given that every member of American society is currently exposed to these pollutants, this study has the potential to contribute to devising effective strategies aimed at protecting millions from the untoward effects of these pollutants.

What are the possible risks or discomforts involved with being in this study?
This study might involve the following risks and/or discomforts to you:

If you have any tendency to become uncomfortable in small closed spaces, it is possible that you may become uncomfortable during this study. You will be taken to the exposure chamber when you are first evaluated for suitability for the study to allow you an opportunity to see where you will sit and what the chamber looks like.

Diesel exhaust exposure: Exposure to air pollution particles can cause cough, shortness of breath, chest discomfort, eye irritation, and headache. These symptoms typically last no more than a few hours, but could last longer if you are especially sensitive. Eye wear protection goggles are available during the exposures to reduce possible eye irritation. There is a chance that exposure to particles can increase the likelihood that you will be more likely to come down with a respiratory infection within several days of the exposure. Diesel exhaust, even when diluted in this study, may have an unpleasant odor. Exposure to the air pollution particle concentrations used in this study for short periods of time has not been found to cause permanent health effects. However, some studies suggest that older people, particularly those with underlying cardiovascular diseases, are at increased risk for getting sick and even dying during episodes of high air pollution. While we can not exclude the possibility that you may have an adverse reaction to breathing these exhausts, you will only be exposed to them for 2 hours. You could be potentially inhale a similar amount if you visited a large city such Los Angeles, New York, or Mexico City on a smoggy day.

You will be monitored continuously during the exposure session through a window in the chamber or by closed-circuit television, and can communicate with a staff member via an intercom. Your heart rate and rhythm will also be constantly monitored for any adverse changes brought about by the exposure. A licensed physician is always on the premises (i.e., within the building facility) during exposures, and is available to respond in an emergency.

Ozone exposure: Potential risks may include mild decrements in lung function spirometric volume, irritation to the nose, eyes, throat and airways, pain on deep inspiration and cough. These symptoms typically disappear 2 to 4 hours after exposure, but may last longer for particularly sensitive people. Ozone may induce an inflammatory reaction that may last for about 24 hours after exposure and may increase your chance of catching a cold.

Diesel exhaust and ozone exposure combined: Because this exposure scenario has not been conducted at our facilities or elsewhere before, we do not yet know whether or not this exposure will include the same risks as diesel exhaust and ozone exposures alone. It is possible that the combination of diesel exhaust and ozone exposures will increase the effects of each pollutant individually, and it is also possible that it will not. We are doing this study in order to find out the answer.

Heart rhythm monitoring: There is little risk associated with monitoring your heart by ECG or blood oxygen by pulse oximetry. However, preparing your skin for placement of ECG electrodes and removing the electrodes the next day may cause some irritation or skin discoloration, itching, or burning in some people. If this occurs during your visit, you should tell the nursing staff. If irritation occurs while you are home, you should remove the electrodes, wash gently with mild soap and water, and tell the study coordinator or nursing staff in the morning.

Blood pressure monitoring: Similar to the regular blood pressure measurement, the risk associated with blood pressure monitor is considered minimal.

Venous blood sampling: The risks associated with taking blood samples are considered minimal. A well-trained member of the staff will draw the blood. Drawing blood could cause some bruising or minor pain, which usually resolves quickly. Occasionally fainting or light-headedness occurs, and injury is minimized by having you seated. Also, a rare complication is skin infection or an infection of the vein in which the blood has been drawn. The risk of getting infection is minimized by the use of sterile technique. If you do have signs of infection at the site (redness, warmth, painful skin, and swelling) after completion of the procedure, you will need to contact the EPA medical station.

Exhaled breath collection: Minimal risk is associated with these procedures. Sensitive individuals may become light-headed. You will be seated in a chair during collections and technicians are always available during this procedure in case you become light-headed.

Breathing tests (spirometry): You may cough or become dizzy during these tests. You will be seated in a chair, and if these symptoms occur, they are usually only temporary. You will be exposed to a low dose of acetylene for a brief period of time (single breath in and breath out), thus the risk will be quite low.

In addition, there may be uncommon or previously unrecognized risks that might occur. If you do notice any unusual symptoms occurring during the study you should call the EPA medical station or the on-call physician to report them. We will give the number of the physician on-call before you leave the building.

Genotyping: If given permission to collect genetic information, a federal law called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans and most employers to discriminate against you based on your genetic information. GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance or long term care insurance. GINA dose not protect you against discrimination based on an already diagnosed genetic condition or disease.

What if we learn about new findings or information during the study?

You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will your privacy be protected?

You will be given a study code number. All electronic documents will only have that number. The paper records that the coordinators and medical doctors use may have your name. Your information can be linked to your personal information by the study number, however only study personnel have access to your personal information. Paper records that use your name are kept in a locked file cabinet in the EPA Medical Station of the Human Studies Facility. The Medical Station is locked when not attended by study staff, and the EPA Human Studies Facility has

limited access to authorized individuals only, 24 hours/day for 7 days/week. Blood samples will be stored at the EPA Human Studies Facility.

Research studies may be done at many places at the same time. Your personal identifying information will never be sent to outside researchers.

No subjects will be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies for purposes such as quality control or safety.

What will happen if you are injured by this research?
All forms of human health research involve some risk of injury or illness. Despite our high level of precaution, you may develop an injury or illness due to participating in this study. If you develop an injury or illness determined by an appointed US EPA physician to be due to your participation in this research, the US EPA will reimburse your medical expenses to treat the injury or illness up to $5000. If you believe your injury or illness was due to a lack of reasonable care or other negligent action, you have the right to pursue legal remedy. The Federal Tort Claims Act, 28 U.S.C. 2671 et. Seq., provides for money damages against the United States when personal injury or property loss results from the negligent or wrongful act or omission of any employee of the EPA while acting within the scope of his or her employment. Signing this consent form does not waive any of your legal rights or release the investigator, the sponsor, the institution, or its agents from liability for negligence.

If a research related injury or illness occurs, you should contact the Director of the EPA NHEERL Human Research Protocol Office at (919) 966-6217.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

Will you receive anything for being in this study?
You will be paid approximately $12 per hour for your participation in this study and the total compensation for completion of this study will be approximately $3,738.00

We will give you parking coupons to cover the cost of parking. If you live beyond Chapel Hill you will be reimbursed for mileage at the US Government mileage rate in effect at the time. Money received by participants in research studies is normally treated as ordinary income by taxing authorities and we will report payments made to you to the Internal Revenue Service as required by law. Payments totaling more than $600 in a year from a single or multiple EPA studies will be reported to the IRS. This summary is to emphasize the importance of all the visits, and to signify the importance of your time and commitment to the research study. Below is a detailed list of compensation for the entire study.

Subject Compensation for Procedures during Diesel and Ozone Exposure Study

Training Day (assume 3 hr @$12/hr)	$36
First Exposure:	
Day 1	
Hourly payment (assume 8 hr @$12/hr)	$96
On-time bonus (8 a.m.)	$25
Stress questionnaire	$2.50
Blood Draw (twice)	$30
24 hr Urine Collection	$60
Exhaled breath and saliva collection (twice)	$10
24 hr Holter Monitoring	$100
24 hr Blood Pressure Monitoring	$50
Lung function (6x)	$60
Lunch	$5
Day 2	
Hourly payment (assume 8 hr @$12/hr)	$96
On-time bonus (8 a.m.)	$25
Blood Draw (twice)	$30
Urine Sample (3x)	$15
Exhaled breath and saliva collection (twice)	$10
24 hr Holter Monitoring	$100
24 hr Blood Pressure Monitoring	$50
Lung function (6x)	$60
Lunch	$5
Day 3	
Hourly payment (assume 3 hr @$12/hr)	$36
Blood Draw	$15
Exhaled breath and saliva collection	$5
Urine Sample	$5
Lung function	$10
[Total payment First Exposure]	$900.50
Second Exposure	$900.50
Third Exposure	$900.50

Fourth Exposure	$900.50
Completion Bonus (for completing all 4 exposure sessions)	$100
APPROXIMATE TOTAL (including training day)	$3,738.00

Additional blood draws ($10 each)
Additional hours ($12 per hour)

You should understand that your participation is voluntary. You may terminate your participation in the study at any time without penalty. If you voluntarily elect to withdraw from the study at any time or you fail to maintain compliance with eligibility requirements, you will be paid for that portion of the study that has been completed. Subjects who are dismissed by the investigators after enrollment in the study but prior to completion for involuntary reasons, will be compensated for his/her participation up to that point and will receive compensation at the hourly rate of $12 per hour for the scheduled 3 day study session for a total of $228.

In the event a scheduled study activity must be cancelled by the investigators with less than 72 hours prior notice, the subject will be paid at the standard hourly rate for the time scheduled and canceled, and will be paid 50% of procedure fees up to a total maximum of $100 for canceled procedures. You will be paid in full for any procedures that may have been started during the current visit. Cancellations could occur due to adverse weather conditions, equipment failure, or other unforeseen events. When feasible, you will be rescheduled.

Will it cost you anything to be in this study?
There will be no cost to you for participating in the study. However, if you are deemed not eligible to participate in the study for medical reasons, we may suggest that you seek follow-up care from your own health care provider for abnormalities discovered during the screening history, physical examination, or the study. **Such care is entirely at your own expense. EPA will not provide reimbursement for any follow-up care.**

All study procedures will be paid for by the study. We will give you parking coupons to cover the cost of parking. If you live beyond Chapel Hill you will be reimbursed for mileage at the US Government mileage rate in effect at the time.

This study will take approximately 10 weeks to complete. The study duration is based on 4 exposure regimes separated by at least 2 weeks. The total amount of time at this facility will be ~79 hr.

What if you are a UNC student?
You may choose not to be in the study or to stop being in the study before it is over at any time. This will not affect your class standing or grades at UNC-Chapel Hill. You will not be offered or receive any special consideration if you take part in this research.

What if you are a UNC employee?
Taking part in this research is not a part of your University duties, and refusing will not affect your job. You will not be offered or receive any special job-related consideration if you take part in this research.

Who is sponsoring this study?
This research is funded by The U.S. Environmental Protection Agency. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have further questions regarding this study, you should call one of the listed investigators:

Michael Madden, PhD	919-966-6257	David Diaz-Sanchez, PhD	919-966-0676

If you feel a research-related injury has occurred, please contact the HSF medical station or one of the investigators listed above. In addition, you should contact the Human Studies Division Human Research Officer and Director of the National Health Effects and Environmental Research Laboratory Human Research Protocol Office at 919-966-6217.

What if you have questions about your rights as a research subject?
All research on human subjects is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously, if you wish, the Institutional Review Board at 919-966-3113 or by email to IRB_ subjects@unc.edu and/or the EPA Director of the National Health and Environmental Effects Human Research Laboratory Protocol Office at 919-966-6217.

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IRB Study #_09-1344___Title of Study: Cardiopulmonary Responses to Exposure to Ozone and Diesel Exhaust with Moderate Exercise in Healthy Adults

Principal Investigator: Michael Madden, PhD

Subject's Agreement to Participate in the Research Study WITHOUT Genotyping Consent

I have read the information provided above. I have asked all questions I have at this time. I voluntarily AGREE to participate in this study and I REFUSE to have my cells genotyped for any genes decided by the study investigators.

_____ _____

Signature of Research Subject Date

_____

Printed Name of Research Subject

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent

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Subject's Agreement to Participate in the Research Study Genotyping Consent

I have read the information provided above. I have asked all questions I have at this time. I voluntarily AGREE to participate in this study and I voluntarily AGREE to have my cells genotyped for any genes decided by the study investigators to be related to adverse health effects associated with pollution exposure.

_____ _____

Signature of Research Subject Date

_____

Printed Name of Research Subject

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent